# PATENT COOPERATION TREATY



### INTERNATIONAL PRELIMINARY EXAMINATION REPORT (PCT Article 36 and Rule 70)

Applicant's or agent's file reference 2002.017 WO  FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)						nal		
International application No.				International filing date	(day/montf		Priority date (day/month/ye	
PCT/EP 03/10696			696	19.09.2003			20.09.2002	
International Patent Classification (IPC) or both national classification and IPC C07K14/45								
Appli		<b></b> -						
AZK	O NO	ORFI	. N.V. et al.					•
<ol> <li>This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</li> </ol>								
2.	2. This REPORT consists of a total of 4 sheets, including this cover sheet.							
	This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).							
	These annexes consist of a total of sheets.							
3.	This	repo	t contains indications re	elating to the following it	ems:			•
	1	$\boxtimes$	Basis of the opinion					
	11		Priority					
	111		Non-establishment of	opinion with regard to n	ovelty, in	ventive step a	nd industrial applicability	
	IV		Lack of unity of inventi				,	
	V	Ø	Reasoned statement uncitations and explanations	under Rule 66.2(a)(ii) w ions supporting such st	ith regard atement	to novelty, inv	ventive step or industrial	applicability;
	VI		Certain documents cite	ed				
	VII			international application				
	VIII		Certain observations of	on the international appl	lication			
Date of submission of the demand  Date of completion of this report								
26.03.2004				27.12.	2004			
Name and mailing address of the international preliminary examining authority:  Authorized Officer					Gurbas Petrasian			
European Patent Office D-80298 Munich Schwachtgen, J-L								
Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465				556 epmu d		ne No. +49 89 2	399-8933	

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## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

REC'D	29	DEC	2004
<b>IDOA</b>	/ED	024	0606-

l. Basis	of	the	repo	rt
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**Description, Pages** 

 With regard to the elements of the international application (Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)):

	1-3	33	as originally filed					
	Se	Sequence listings part of the description, Pages						
	1-1	5	as originally filed					
	Cla	aims, Numbers						
	1-2	20	as originally filed					
	Drs	awings, Sheets						
		8-28/28						
			as originally filed					
2.	Wit lan	h regard to the lang guage in which the ir	uage, all the elements marked above were available or furnished to this Authority in the item.					
	The	ese elements were a	vailable or furnished to this Authority in the following language: , which is:					
		the language of a tr	anslation furnished for the purposes of the international search (under Rule 23.1(b)).					
		the language of put	plication of the international application (under Rule 48.3(b))					
		the language of a tr Rule 55.2 and/or 55	anslation furnished for the purposes of internal to the purpose of internal to the purpose of the pu					
3.	Witl inte	h regard to any <b>nucl</b> rnational preliminary	eotide and/or amino acid sequence disclosed in the international application, the examination was carried out on the basis of the sequence listing:					
			ernational application in written form.					
		filed together with th	ne international application in computer readable form.					
		furnished subseque	ntly to this Authority in written form.					
		furnished subseque	ntly to this Authority in computer readable form.					
			the subsequently furnished written sequence listing does not go beyond the disclosure application as filed has been furnished.					
		The statement that the listing has been furn	he information recorded in computer readable form is identical to the written sequence ished.					
ŀ.	The	amendments have r	esulted in the cancellation of:					
		the description,	pages:					
		the claims,	Nos.:					
		the drawings,	sheets:					

### INTERNATIONAL PRELIMINARY **EXAMINATION REPORT**

International application No.

PCT/EP 03/10696

This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)

Yes: Claims

1-17, 19, 20

No: Claims 18

Inventive step (IS)

Yes: Claims

1-17, 19, 20

No:

Claims

18

Industrial applicability (IA)

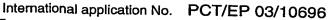
Yes: Claims

1-20

No: Claims

2. Citations and explanations

see separate sheet



#### Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Reference is made to the following documents:

D1: WO 98/37185 A (HU SHI XUE ;UNIV TEXAS (US); XU HONG JI (US); ZHOU YUNLI (US); LOG) 27 August 1998 (1998-08-27)

D3: WO 00/66154 A (ZUTHER ELLEN ;LYONS RUSSELL (GB); ROBERTS CRAIG (GB); ROBERTS FION) 9 November 2000 (2000-11-09)

The present application does not meet the criteria of Article 33(1) PCT, because the 2. subject-matter of claim 18 is not new in the sense of Article 33(2) PCT.

The document D1 discloses a DNA fragment comprising a heterologous protein, ie p53, rb, TNF or a truncated part thereof, fused to the N-terminal part of a tetrepressor protein Claims 3 and 20-28; Examples). The disclosure in D1 anticipates all the features of the subject-matter of claim 18 of the present application. Even if novelty could be established, the subject-matter of claim 18 would represent an obvious modification (Article 33(3) PCT) of the disclosure in D1 as a solution to the problem of providing an alternative DNA fragment comprising a heterologous protein fused to the N-terminal part of a tet-repressor protein

D2 is regarded as being the closest prior art to the subject-matter of claims 1-17 and 3. 19-20. D2 discloses a live attenuated parasite having knocked out essential genes from which the subject-matter of the present application differs by the use of a conditional inducible knockout of a ribosomal protein gene.

None of the cited prior art documents, either alone or in combination, appear to disclose the subject-matter of said claims, which thus meet the requirements of Article 33(3) PCT.